K021243

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc
B.	Company Address:	6354 Corte del Abeto Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 918-1823
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

A.	Trade Name:	ILT Torquer
B.	Catalog Number:	A114TR1
C.	Common Name:	Torquer
D.	Classification Name:	Catheter Guide Wire Accessory
E.	Device Class:	Class II (per 21 CFR 870.1330)

INDENTIFICATION OF PREDICATE DEVICE

The ILT Torquer is substantially equivalent to the Boston Scientific Corporation wireClip™ cleared under 510(k) K003398.

DEVICE DESCRIPTION

The IntraLuminal Therapeutics Torquer is a plastic device that allows for manipulating and directional control of a guide wire. The Torquer will accommodate commercially available guide wires ranging in size from 0.014" to 0.035". The Torquer can be side-loaded onto the guide wire after the wire is in place within the catheter. When the finger tabs of the ILT Torquer are squeezed and the jaws of the ILT Torquer open, the guide wire can be placed inside. Releasing the finger tabs allows the jaws to close, capturing and firmly gripping the guide wire.

The ILT Torquer is packaged in a Tyvek®/mylar pouch that is heat-sealed to form a sterile barrier. The packaged units are sterilized with ethylene oxide gas. The device is provided "STERILE", and is intended for single use only.

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INTENDED USE

The Torquer is indicated for use in manipulating a guide wire in order to access discreet regions of the vasculature.

TECHNOLOGICAL CHARACTERISTICS

The ILT Torquer is similar in basic materials, design, construction and mechanical performance to the predicate device.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing is not required for ILT Torquer because there is no patient contact. *In vitro* bench studies were conducted to evaluate the performance characteristics of the ILT Torquer. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the ILT Torquer is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

IntraLuminal Therapeutics, Inc.
c/o Ms. Pamela Misajon
6354 Corte del Abeto, Suite A
Carlsbad, CA 92009

Re: K021243
ILT Torquer
Regulation Number: 870.1330
Regulation Name: Catheter Cannula
Regulatory Class: II (two)
Product Code: DQX
Dated: April 18, 2002
Received: April 19, 2002

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021243

INDICATIONS FOR USE

510(k) Number:

Device Name: ILT Torquer

Indications for Use: The Torquer is indicated for use in manipulating a guide wire in order to access discreet regions of the vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K021243